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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/670,568	09/27/2000	Yoji Ikawa	Q61014	5597

7590 03/12/2002
Sughrue Mion Zinn Macpeak & Seas PLLC
2100 Pennsylvania Avenue NW
Washington, DC 20037-3213

EXAMINER

DAVIS, NATALIE A

ART UNIT	PAPER NUMBER
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1642

17

DATE MAILED: 03/12/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/670,568

Applicant(s)

IKAWA ET AL.

Examiner

Natalie A. Davis

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 11 December 2001.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-3, 5-8, 16 and 19-21 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 1, 3, 16 and 19-21 is/are allowed.
- 6) ☒ Claim(s) 2 and 5-8 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☒ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ 6) ☐ Other: _____

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DETAILED ACTION

Applicant's amendment and request for corrected filing receipt filed 11 December 2001 (Paper No: 16) is acknowledged. Accordingly, claims 1-3, 5-8, and 16 are amended, claims 4, 9-15, and 18 are cancelled, and claims 19-21 are new. Claims 1-3, 5-8, 16, and 19-21 are pending.

Response to Arguments

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Oath/Declaration

The oath or declaration is defective. A new oath or declaration in compliance with 37 CFR 1.67(a) identifying this application by application number and filing date is required. See MPEP §§ 602.01 and 602.02.

The oath or declaration is defective because: it does not claim priority to PCT/JP99/01512, as is required for a National Stage 35 U.S.C. § 371 application. 7

Priority

1. Applicant's claim for foreign priority under 35 U.S.C. § 371 is acknowledged, but applicant has not complied with one or more conditions for receiving the benefit of an earlier filing date, as indicated above. Accordingly, the response to the amendment has been rendered as if priority has been granted.

Claim Rejections - 35 USC § 112 2nd Withdrawn

2. Rejection of claims 15-16 under 35 U.S.C.112, second paragraph is withdrawn in view of arguments and cancellation of claim 15.

Claim Rejections - 35 USC § 112 1st Withdrawn

3. Rejection of claims 1-2, 4-8, and 15-17 under 35 U.S.C.112, first paragraph is withdrawn in view of arguments and cancellation of claims.

Claim Rejections - 35 USC § 102 Withdrawn

4. Rejection of claims 1-2, 4-8, and 15-18 over Yang, et al. (1998), McKeon, et al. (1999), and Osada, et al. (1998) under 35 U.S.C. 102(b,e) is withdrawn in view of priority to PCT/JP99/01512, filed 24 March 1999 and foreign application JAPAN 10/100467, filed 27 March 1998.

New Claim Rejections - 35 USC § 112

5. Claims 5-8 are rejected under 35 U.S.C. 112, first paragraph. The instant specification does not contain a written description of the invention in such full, clear, concise, and exact terms or in sufficient detail that one skilled in the art can reasonably conclude that applicant had possession of the claimed invention at the time of filing.

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cancelled

Vas-Cath Inc. v. Mahurkar (CA FC) 19 USPQ2d 1111 (6/7/1991) clearly states that "written description" of invention required by first paragraph of 35 U.S.C. 112 is separate and distinct from that paragraph's requirement of enabling disclosure, since description must do more than merely provide explanation of how to "make and use" invention; applicant must also convey, with reasonable clarity to those skilled in art, that applicant, as of filing date sought, was in possession of invention, with invention being, for purposes of "written description" inquiry, whatever is presently claimed. An applicant shows possession by describing the claimed invention with all its limitations using such descriptive means as words, structures, diagrams, and formulas. Also, description of an actual reduction to practice, or by showing the invention was "ready for patenting," or by describing distinguishing identifying characteristics sufficient to show that the applicant was in possession of the claimed invention at the time of filing.

The claims are drawn to an isolated DNA molecule, which hybridizes under stringent conditions to 1-2186 and 145-1488 nucleotides of DEQ ID NO: 2, a primer and a probe comprising a DNA molecule, which hybridizes under stringent conditions to 1-2186.

There is no descriptive information, such as how the DNA molecule hybridizes to nucleotides 1-2186 and 145-1488 of SEQ ID NO: 2, whether or not it hybridizes to every nucleotide and if not which nucleotides the DNA hybridizes to. There is no detailed description of the function of the DNA in claims 5-6 indicating that the claimed DNA was indeed identified,

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isolated, and assayed for use. Thus, one skilled in the art would not recognize from the disclosure that the applicant was in possession of the DNA.

Claim Rejections - 35 USC § 102

6. Claims 2 and 5-8 are rejected under 35 U.S.C. 102(b) as being anticipated by Fu, et al. (1995).

Claims 5-8 are anticipated as Fu, et al., disclose PCR primers and probes, which hybridize under stringent conditions to DNA molecules. It is inherent that the primers and probes set forth hybridize to nucleotides 1-2186 and 145-1488 of SEQ ID NO: 2, since hybridization requires the pairing of a single nucleotide base of two nucleic acid strands which are complementary.


Likewise, claim 2 is anticipated since a PCR primer (as taught by Fu) may control transcription by binding to the transcriptional start site and inhibiting the start of transcription. Accordingly, the invention is anticipated as claimed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Natalie A. Davis whose telephone number is 703-308-6410. The examiner can normally be reached on M-F 8-5:30 (every other Friday off).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anthony Caputa PhD can be reached on 703-308-3995. The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-4315 for regular communications and 703-308-4556 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

Natalie A. Davis, PhD
March 5, 2002


ANTHONY C. CAPUTA
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600